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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,530	09/18/2006	Janel Birk	18006 PCT US (INA)	4476
51957	7590	09/15/2010		
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599			EXAMINER ISHMAN, NAQUAN ERIC	
			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			09/15/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,530	<b>Applicant(s)</b> BIRK ET AL.	
	<b>Examiner</b> NAQUAN ISHMAN	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 21-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/30/07, 4/16/07, 8/01/08, 6/05/09</u> .                      | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 21-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on June 1, 2010.

### ***Specification***

2. The disclosure is objected to because of the following informalities: "form," on page 2, line 33 should be "from."

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 4-5 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Garay et al. (4,925,446).

5. Garay et al. disclose a gastric balloon (26) comprising: a shell (27); a receiver formed in said shell (Portion of shell that receives tubing 12, see Fig. 5); a valve (21) for preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (12) in fluid communication with the shell house in said receiver and extendable from the stomach of a patient to the mouth of the patient (See Col. 3, lines 1-9), wherein said shell is inflated and

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deflated from outside the body of the patient via said retractable tubing (Col. 3, lines 1-9). (See Fig. 5).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-3 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al. (4,925,446) in view of Mouri et al. (6,074,378).

8. Garay et al. disclose the invention essentially as claimed except for said retractable tubing is formed in one or more spirals or in a coil.

9. Mouri et al. disclose a self retaining catheter (10) comprising a catheter body (11) having a lumen and made of a shape memory material (Col. 5, lines 52-55). The catheter body (11) has a shape memory coil wire (14) buried inside of it (Col. 5, lines 66-67 and Col. 6, lines 1-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the tubing (12) of Garay et al. with the catheter body having an embedded coil of Mouri et al. in order to allow the tubing to recoil to a smaller profile after inflation of the balloon to prevent damage to the inner wall of the stomach (Col. 2, lines 29-34).

10. Regarding claim 11, Mouri et al. also disclose the catheter (11) may be formed from is formed of a soft material (urethane, Col. 5, line 53).

11. Regarding claim 12, Mouri et al. also disclose the catheter (11) may be formed of s semi-rigid material (shape memory alloy, Col. 5, line 55).

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12. Claims 6-7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al. (4,925,446) in view of Gau et al. (5,084,061).

13. Garay et al. disclose the invention essentially as claimed except wherein said receiver is a molded valve patch bonded to the shell.

14. Gau et al. disclose an intragastric balloon (20), comprising a self sealing valve (28) and a valve cover patch (34, examiner also interprets this to be a cap) that is affixed to the exterior of the balloon shell using an adhesive (Col. 5, lines 34-36). The valve cover patch of Gau et al. has an "X" shaped slot (36) that is aligned with a hole (38) in the shell of the balloon for insertion of an inflation tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the valve patch system of Gau et al. to the receiver of Garay et al. in order to provide a barrier means at the surface of the balloon to prevent deflation of the balloon if the inflation tube were accidentally separated from the balloon.

15. Claims 1 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al. (4,925,446) in view of Cheng (4,693,695).

16. Garay et al. disclose a gastric balloon (26) comprising: a shell (27); a valve (21) preventing the undesired addition or elimination of fluid from the gastric balloon; and a retractable tubing (12) extendable from the stomach of a patient to the mouth of the patient (See Col. 3, lines 1-9), wherein said shell is inflated and deflated from outside the body of the patient via said retractable tubing (Col. 3, lines 1-9). (See Fig. 5). Garay et al. do not disclose a receiver for housing the retractable tubing.

17. Cheng discloses a balloon (12) having a receiver (42) which divides the balloon into two hemispheres (18/20) and houses a retractable tether (14) (Figs. 4-5). It would have been obvious

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to one having ordinary skill in the art at the time the invention was made to make the balloon of Garay et al. with two hemispheres connected by a receiver that provides fluid communication to both hemispheres as disclosed by Cheng, such that the retractable tubing (12) is in fluid communication with the receiver, in order to provide a means for decreasing the profile of the tubing once the gastric balloon reaches the gastric lumen.

18. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al. (4,925,446) in view of Adams (US 2002/0183765 A1).

19. Garay et al. disclose the invention essentially as claimed except wherein said valve is a slit valve.

20. Adams discloses a slit valve (104) contained in an inflation lumen (104) used to inflate a balloon (106). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the valve of Garay et al. with the slit valve of Adams in order to permit passage of the balloon inflation fluid in one direction only (Adams, Para [0077]).

21. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al. (4,925,446) in view of Trick (4,417,567).

22. Garay et al. disclose the invention essentially as claimed except wherein said valve is a septum.

23. Trick discloses a balloon (18) having an elongated stem which is closed with a septum (24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the valve of Garay et al. with the septum of Trick in order to allow inflation fluid to be added to or removed from the inflation tube leading to the balloon by a hollow needle (Trick, Col. 2, lines 64-68, and Col. 3, lines 1-2).

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24. Claims 15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al. (4,925,446) in view of Cheng (4,693,695), as applied to claim 1 above, and further in view of Ekich (US 6,474,584 B2).

25. Garay et al. and Cheng disclose the invention essentially as claimed except for a torsionally loaded axle, wherein said torsionally loaded axle resists removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing; wherein said torsionally loaded axle is located horizontally with respect to said receiver or wherein said torsionally loaded axle includes a pre-grooved surface for accommodating said retractable tubing.

26. Ekich discloses a spring loaded bobbin (10) with a spool (14) having thread guides for accommodating thread (See Figs. 1 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made dispose the spring loaded bobbin over the spool of Garay et al., modified by Cheng, such that the tubing (12) is accommodated by the thread guide, in order to provide a means retract the tubing (12) into the receptacle of Garay et al. and Cheng, after the balloon is inflated.

27. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garay et al. (4,925,446) in view of Ekich (US 6,474,584 B2).

28. Garay et al. disclose the invention essentially as claimed except for a torsionally loaded axle which resist removal of said retractable tubing from said receiver and returns said retractable tubing to said receiver for housing; wherein said torsionally loaded axle is located vertically with respect to said receiver.

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29. Ekich discloses a spring loaded bobbin (10) with a spool (14) having thread guides for accommodating thread (See Figs. 1 and 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made dispose the spring loaded bobbin over the receiver portion of Garay et al. such that the tubing (12) is accommodated by the thread guide, in order to provide a means retract the tubing (12) into the receptacle area of Garay et al. after the balloon is inflated.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAQUAN ISHMAN whose telephone number is (571) 270-7783. The examiner can normally be reached on Monday through Friday 10am until 7pm (Off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/N. I./

Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734